

510(k) Summary of Safety and Effectiveness

1.0 Classification Name:

Set Laparoscopy

2.0 Common/Usual Name:

Veress Cannula Spring Loaded, Telescopes

3.0 Trade Name:

Mini Laparoscopes

4.0 Equivalence:

These devices are equivalent to existing pre-enactment devices sold by Richard Wolf and 510(k) devices sold by Imagyn, Ethicon, and Origin.

5.0 Description:

Cannula and tubes are made of medical grade stainless steel and chrome plated brass.

Telescopes are made of medical grade stainless steel (sleeve), glass-lenses, glass-fibers, brass chrome plated (housing) and plastic (eyepiece).

6.0 Intended Use:

The Miniature Laparoscope Set is used to apply and maintain pneumoperitoneum in the usual way, and to introduce telescopes and other auxiliary instruments, such as forceps and scissors for diagnostic and therapeutic purposes.

7.0 Technological Characteristics:

As the intended use describes, the set is miniaturized in diameter and length for minimal invasive laparoscopy. The veress cannula and the tubes are larger in diameter and longer in working length, the telescopes are shorter in length and smaller in diameter.

8.0 Performance Data:

Instruments have been tested to assure the function of the spring loaded cannula and the possibility of steam autoclaving.

9.0 Clinical Tests:

No clinical tests performed.

10.0 Data Conclusion:

The mentioned R. Wolf Mini Laparoscopy devices are substantially equivalent to existing devices on the market. They have been tested to allow safe usage, with no significant changes during the standard lifetime, when used according to our instructions.

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